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First Named Inventor	Kent L. Christopher
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ENCLOSURES *(check all that apply)*

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Request for Reconsideration

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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Date	December 18, 2002

CERTIFICATE OF MAILING

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Kent L. Christopher

Serial No. 09/818,228

Filed: March 27, 2001

For: METHOD AND APPARATUS FOR PHARYNGEAL AUGMENTATION OF VENTILATION

Examiner M. Patel
Group Art Unit 3761

Commissioner for Patents
Washington, D.C. 20231

REQUEST FOR RECONSIDERATION

Applicant respectfully submits the following in response to the Office Action dated September 23, 2002:

Claims 1 - 4, 8, 11 - 17, 19, 20, 23, and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke. Claims 5, 6, and 18 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Dali et al. Claims 7 and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Spofford et al. Claims 9, 10, 21, 22, 26, and 27 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Brekke in view of Daniell et al.

In response, Applicant notes that the subject matter of this invention pertains to the field of pulmonary medicine, particularly the treatment of respiratory failure/insufficiency and sleep apnea. To fully understand the importance of the structure of the present invention and to completely understand the distinct benefits that result from the intended use of the present invention, it is important to have knowledge of the pathophysiology of respiratory failure, respiratory insufficiency, and sleep apnea.

Respiratory failure and insufficiency occur when diseases or disorders of the respiratory system prevent carbon dioxide from being exhaled and/or inadequate amounts of oxygen from entering the blood during spontaneous breathing of ambient or atmospheric air. When there is an impairment of the alveolocapillary membrane,

mismatch of ventilation and blood flow, or underventilation due to a lung disease or disorder, inadequate amounts of oxygen may enter the blood during spontaneous breathing of ambient or atmospheric air. Respiratory failure and insufficiency can be acute, chronic, or acute superimposed upon chronic. Respiratory failure and insufficiency can cause carbon dioxide retention because:

1. The respiratory muscles fatigue due to increased work of breathing and the consequence is inadequate spontaneous breathing of ambient air; and/or

2. Impaired central ventilatory drive results in inadequate spontaneous breathing of ambient air in and out of the lungs.

Similarly, sleep apnea occurs when, during spontaneous breathing of ambient or atmospheric air, inadequate volumes of air reach the lungs (causing low blood oxygen levels) and carbon dioxide is not adequately exhaled. Sleep apnea can be caused by:

1. Upper airway obstruction, where tissue planes in the upper airway are "sucked" together causing obstruction on inspiration. Inadequate spontaneous breathing of ambient air then occurs. With total occlusion, there is cessation of breath, or "apnea," and with partial obstruction there is an inadequate breath (hypopnea), which often generates a snoring sound. Obstruction is often at the level of the soft palate. Uvulopalatopharyngoplasty (the surgical removal of this level of obstruction) corrects sleep apnea in about 50% of patients, demonstrating that the significant obstruction is at this level in about 50% of patients. A second area of obstruction is often at the base of the tongue and hypopharynx; and/or

2. Impaired central ventilatory drive which also results in inadequate spontaneous breathing of ambient air in and out of the lungs.

The Brekke Device. The Brekke device is intended to use in the field of oral surgery, specifically the administration of anesthetics or oxygen for surgical procedures with access to the oral cavity face and neck (column 1, lines 5 - 7). Brekke teaches "An oral-pharyngeal tube having a single inflatable barrier for sealing contact with the base of the tongue, soft palate and lateral pharyngeal walls together with a fluid supply tube for inflating the inflatable barrier and a device for connecting one of the cannula leads to the other end of the tube" (abstract).

Integral to the nasalpharyngeal tube is an inflatable member (18a in figure 1a, or 18 in figure 1). The member is inflated with air to assume and maintain its functional configuration, and is therefore airtight. The inflatable barrier seals contact with the base of the tongue, soft palate and lateral pharyngeal walls, completely blocking the entire oral cavity. The seal is intended to be more complete than a "gauze sponge", and the purpose of the barrier is to prevent unknown foreign matter and surgical debris from passing into the trachea and lungs (column 1, lines 26 - 28 and 54 - 62). The distal opening of the nasal pharyngeal tube is also distal to the inflatable cuff 20 and extends into the hypopharynx, rather than the oropharynx, as shown in figure 1 of the Brekke patent. The structure of the inflatable barriers 18, 20 of Brekke's nasalpharyngeal tube (which must be inflated to perform the intended function) totally obstruct the airway and effectively prevent spontaneous breathing of ambient air through the mouth.

The purpose of the cannula is to provide a positive air seal with the nose for more efficient administration of gases in environment II (column 2, lines 16 - 18). Likewise, the compressible nose bulbs on the cannula provide an effective seal for the device preventing leaking of anesthetic gases into the operatory and the patient's inhalation of ambient air (column 2, lines 53 - 56). In other words, the cannula inhibits spontaneous breathing of ambient air through the nose. The cannula has supply tubes 40 and 42 that serve as the supply of anesthetic gas/oxygen for the inspired breath, and valve 38 is the intended path for exhalation (column 4, lines 24 - 29).

In summary, the Brekke's nasalpharyngeal tube is recommended for use in environment II (column 2, lines 19 - 23), which is an oral surgery office or an outpatient clinic (column 1, lines 9 - 11). In describing environment II, it is noted that an effective seal between the patient and the anesthetic delivery apparatus is important in order to

prevent escape of anesthetic gases and oxygen into the operatory environment and to prevent the patient's inspiration of atmospheric air (thus diluting the effect of the administrated anesthetics or oxygen) (column 1, lines 46 - 53). It is clear that the structure of the Brekke's nasalpharyngeal tube is designed to prevent the spontaneous breathing of ambient air.

Brekke notes that the nasalpharyngeal tube 44 must be positioned so that the inflatable barrier seals against with the base of the tongue, soft palate and lateral pharyngeal walls. "The length of the nasal pharyngeal tube 44 is such that it accommodates a person with a relatively large head and may be adjusted by moving the tube in or out of the nose" (column 4, lines 46 through 48). According to the Brekke's method for insertion of the nasalpharyngeal tube, the patient must first be rendered unconscious by intravenous anesthetics before the tube 44 is inserted (column 5, lines 21 through 22). The tube 44 is then inserted into the nostril four-fifths of its length and the oxygen/anesthetic gas source is turned on (column 5, lines 24 through 26). The tube 44 is then inserted fully as shown in figure 1 (column 5, line 30). After the tube 44 is fully inserted into the nasal cavity, the inflatable barrier 18a is inflated and must seal contact with the base of the tongue, soft palate and lateral pharyngeal walls. If it does not, the operator must move the tube further in or out of the nasal cavity. Brekke only places importance on adjusting the position of the inflatable barrier, and not the position of the tip of the tube. If the tube 44 is positioned totally out of the nose it will dislodge the collar (34 or 36) and the delivery tube (32 or 34). Trimming the length of the tube 44 to adjust the position of the inflatable barrier is not an option. Cutting the proximal end of the tube 44 would destroy the connection of the intubation tube with the cannula nose lead (Figure 10). Similarly, as shown in figures 10 and 6, cutting or trimming the tube 44 would destroy the inflation tube connection 22b and destroy the functionality of the nasalpharyngeal tube. Finally, the proximal end of tube 44 would be difficult to trim or cut because it is located entirely within the nasopharynx after insertion, as shown in Figure 1.

Structure of the Present Invention. The structure and intended use of the present invention are different than that of Brekke. The nasal pharyngeal catheter does

not interfere with the patient's spontaneous of ambient or atmospheric air, as required in each of the claims in the present application. The catheter is passed via one nostril and no collar is present to obstruct the nasal vestibule. The catheter is small enough so that air can still pass through that nostril. Intentionally, the contralateral nostril is totally free of any obstructing collar or other device. The cross-sectional area of the catheter is very small relative to the size of the nasopharynx through which it passes. The contralateral side of the nasopharynx is free of any device. The catheter does not interfere with the spontaneous breathing of ambient or atmospheric air through the nose. When placed into the superior aspect of the oropharynx just below the uvula, the catheter has a very small cross-sectional area relative to the oral cavity and oropharynx. There is no inflatable member to obstruct the oral cavity. The catheter does not interfere with the spontaneous breathing of ambient or atmospheric air through the mouth.

The intended use of the present invention is very different than the intended use of the Brekke device. The purpose of the catheter system is to treat acute and chronic respiratory failure and respiratory insufficiency as well as sleep apnea by augmenting spontaneous breathing of ambient or atmospheric air. In particular, the present invention offers two main benefits for the treatment of respiratory failure and insufficiency:

1. One major benefit of the gas flow through the present catheter is the effect on dead space. Anatomical dead space is the volume contained within the entire upper airway and the tracheobronchial tree. Physiologic dead space is the sum of anatomic dead space plus the volume of dead space gas in nonfunctioning alveoli due to respiratory diseases or disorders. The normal anatomical dead space of the average sized person is 150 ml. The upper airway constitutes the major portion of the anatomical dead space. The total volume displaced by the nasal pharyngeal catheter described in his application is less than 3 to 4 ml. Though the volume of anatomical dead space is smaller in infants and children, the diameter and length of the catheter are proportionately smaller.

The small volume of the catheter relative to the anatomical dead space prevents obstruction of the spontaneous breathing of ambient or atmospheric air.

2. A second major benefit of the catheter design is that the high flow of gas directed at the trachea can generate gas flow and volume into the lungs, reducing required work of breathing and helping correct for the inadequate spontaneous breathing of ambient air in and out of the lungs in the presence of the reduced central ventilatory drive.

Use in Treatment of Respiratory Failure and Insufficiency.

1. **Inadequate amounts of oxygen entering the blood during spontaneous breathing of ambient or atmospheric air.** At the end of exhalation the dead space is filled with gas that exited the alveoli, which is low in oxygen and high in CO_2. At the beginning of the next inspiration, this low oxygen and high CO_2 is re-breathed into the alveoli. With the tip of the catheter in the distal nasopharynx or oropharynx, the high flow of pure oxygen or an oxygen enriched gas washes out the low oxygen/high CO_2 dead space gas into the atmosphere and replaces it with a high oxygen environment. This increases the fraction of inspired oxygen (FIO_2) for the subsequent inspiration and helps correct inadequate blood oxygen levels. Similarly, high flows of pure oxygen or an oxygen-enriched gas mixture delivered from the catheter can directly enter the lungs, improving oxygen delivery. The device corrects for inadequate amounts of oxygen entering the blood during spontaneous breathing of ambient or atmospheric air.

2. **Inadequate amounts of carbon dioxide being exhaled during spontaneous breathing of ambient or atmospheric air.** In a similar fashion to what is described above, the re-breathing of the high CO_2 gas contained within the anatomic or physiologic dead space can be detrimental to individuals who will retain CO_2 due to either respiratory muscle fatigue, impaired central respiratory drive, or both. With the tip of the catheter in the distal nasopharynx or oropharynx, the high flow from the catheter of oxygen or an oxygen enriched gas washes out the high CO_2 dead space gas into the

atmosphere during exhalation. Respiratory failure and insufficiency are improved by washing out the dead space during exhalation, facilitating the exhalation of carbon dioxide during spontaneous breathing of ambient or atmospheric air.

High flows of oxygen or oxygen enriched gas delivered from the catheter during inspiration can directly enter the lungs, reducing the work of breathing required to physically draw the gas in. The flow of gas from the catheter directly into the lungs during inspiration can also washout CO_2 from the tracheobronchial tree. Thus, the flow of oxygen or oxygen-enriched gas from the catheter on inspiration can contribute to the volume of gas delivered to the lungs, which reduces work of breathing by the respiratory muscles and helps correct for the inadequate spontaneous breathing of ambient air in and out of the lungs in the presence of the reduced central ventilatory drive.

Treatment of Sleep Apnea. In sleep apnea, an impaired central ventilatory drive also results in inadequate spontaneous breathing of ambient air in and out of the lungs. As with respiratory failure or insufficiency due to an impaired central ventilatory drive, in the presence of central sleep apnea, the high flow of air or oxygen enriched air from the catheter can contribute to the volume of gas delivered to the lungs, which helps correct for the inadequate spontaneous breathing of ambient air. Furthermore, flow from the catheter on expiration can wash CO_2 out of the dead space and into the atmosphere, which improves the condition.

As noted before, the obstruction and obstructive sleep apnea is often at the level of the soft palate. When the catheter is placed past the soft palate and into the superior aspect of the oropharynx, high flows of gas from the catheter on inspiration bypass the obstruction, improving the flow of gas into the lungs, which helps correct for the inadequate spontaneous breathing of ambient air due to the obstruction. When the obstruction is at the level of the base of the tongue or below, high flows on inspiration can keep the airway from collapsing. Consequently, high inspiratory flows of gas from the catheter can relieve the obstruction at the level of the base of the tongue or below, correcting for the inadequate spontaneous breathing of ambient air due to the obstruction.

Furthermore, flows through the catheter on expiration can keep the opposing mucus membranes in the area of the soft palate and in the areas at the tongue or below from coming in contact, thus reducing the tendency for the airway to collapse on the subsequent inspiration.

Additional Benefits in Treatment of Respiratory Failure/Insufficiency and Sleep Apnea. The design of the present catheter allows it to be inserted without any sedation or alteration of consciousness. The catheter can be inserted by the patient. In contrast, the nasopharyngeal tube of Brekke must be inserted in an unconscious patient to be tolerated. If the Brekke nasopharyngeal tube was inserted in the conscious patient described in the present invention, the tip of the catheter in the hypopharynx would cause a gag reflex to the point of vomiting (in the same fashion that sticking a finger down your throat into the hypopharynx induces vomiting). Furthermore, the presence of an object in the hypopharynx is the strongest stimulus to initiate a swallowing reflex, which would induce aerophagia, or swallowing of gas into the esophagus. This can cause stomach distention and rupture. The presence of an inflated balloon pressing on multiple mucosal surfaces would also cause an intense gag reflex.

The current catheter design allows it to be used continuously in the treatment of acute respiratory failure for a number of days. The current catheter design also allows it to be use nightly for many years in patients with chronic respiratory failure or insufficiency and sleep apnea. The nasopharyngeal tube of Brekke is designed to be used for short operative procedures in medically stable patients.

The present invention allows the awake patient to eat and drink during treatment. The nasopharyngeal tube of Brekke is designed to be used in the classic operative setting or outpatient setting where patients have not been fed and have an empty stomach. Eating or drinking with the tube in place would not be possible with the inflatable oral barrier, but this is not an issue because patients must be unconscious to tolerated it.

Based on the design and intended use of the present catheter, the flow rate is important. As noted previously, gas from the catheter can be delivered directly into the

trachea to increase the volume delivered to the lungs, to increase the oxygen content delivered to the lungs, and to increase the CO_2 that is washed out of the tracheobronchial tree. The flow into the lungs during inspiration and expiration is sinusoidal. The average peak flow during tidal spontaneous breathing of ambient air is approximately 30 L/min. A maximum flow of 40 L/min should be adequate to meet this peak inspiratory flow demand. Furthermore, it is noted that under some conditions the major intended use of the catheter is to wash out the gas in the upper airway dead space and replace it with gases of a different property that flow through the catheter. On the low-end of the flow spectrum are the requirements for flushing out the upper airway of infants and children that have a smaller upper airway dead space volume. The flow rate of 4 L/min will meet these needs.

Favorable reconsideration is respectfully requested.

Respectfully submitted,

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Date: Dec. 18, 2002

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